

Food and Drug Administration, HHS

§ 520.2345c

or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 34795, June 11, 2003]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

(c) *Conditions of use. Dogs—*(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations.* Administer orally; continue treatment until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 59365, Nov. 17, 1994; 63 FR 5255, Feb. 2, 1998]

§ 520.2345b Tetracycline tablets.

(a) *Specifications.* Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor.* For 100, 250, or 500 milligrams per tablet, see No. 000069 in § 510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—*(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations.* Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992]

§ 520.2345c Tetracycline boluses.

(a) *Specifications.* Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsors.* See No. 053501 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No. 000009 in § 510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use. Calves—*(1) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations.* Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(iii) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use specified in paragraph (d)(1)(i) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Amount.* 10 milligrams per pound of body weight per day in two divided doses.